DNA
Procedures for DSU i3 Products

1 Purpose

These procedures address dissemination of DNA testing information performed by the DNA Support Unit for investigative lead, intelligence, or other information (i3) purposes and the preparation and review of DNA Support Unit (DSU) Letters of Analysis (LOAs), an i3 product in the DNA discipline.

As a part of the DSU's research activities using new DNA technologies, such as next generation sequencing (NGS), the DSU engages with external partners to obtain items to simulate the challenging samples often encountered in forensic DNA casework. Through these scientific and technical collaborations, sometimes captured in technical Memorandums of Understanding (MOU), the DSU obtains samples such as historical items in the possession of museums, cultural institutions, and others to optimize and test new and novel forensic DNA testing methods. This testing has also been requested on casework evidence for investigative lead, intelligence, or other information purposes. Given the DSU's non-operational area of responsibility (AOR), its DNA testing is not conducted under the requirements of the FBI Laboratory's American National Standards Institute (ANSI) National Accreditation Board (ANAB) forensic testing accreditation or the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories (QAS). However, DNA testing information obtained from research activities support the unit's ongoing efforts to both enhance and maintain the LD's capacity to conduct high-quality DNA examinations in a skilled, progressive, and responsive manner.

When the DSU's DNA testing information may be of interest to contributors, collaborators, external partners, or other interested parties, the DSU will issue an LOA. The intent of such LOAs is to provide these groups with the data, results, and/or conclusions generated by the DSU for investigative lead, intelligence, or other information purposes and are not intended for use in criminal proceedings.

2 Scope

This document applies to DNA personnel who prepare and/or review LOAs containing DNA testing information performed by the DNA Support Unit.

3 Procedures

The DSU Chief will ensure the use of this procedure as appropriate for testing performed by the DSU. DNA personnel with responsibilities related to the preparation, review, and dissemination of a DSU LOA will follow the requirements in the FBI Laboratory Practices for Providing Investigative Lead, Intelligence, or Information (i3) Products.

3.1 Memorandum of Understanding (MOU)

3.1.1 The DSU Chief will ensure collaborations with external partners are documented by a technical MOU, when necessary.

3.1.2 If a collaboration requires a technical MOU, the MOU should capture the collaborator expectations, the testing limitations, the sample(s), data, and result sharing mechanisms (e.g., scientific journal publication, etc.), and the sample disposition (e.g., sample consumption, return, etc.).

3.2 Testing

3.2.1 The testing performed for inclusion in an LOA are typically procedures under development and not yet through the validation process. As such, testing will be conducted by individuals authorized to perform development, modification, verification and validation of methods.

3.2.1.1 A DSU Research Biologist will direct and/or perform the appropriate testing, ensure testing and results are comprehensively recorded and retained and communicate DNA findings verbally and/or in an LOA, as appropriate.

3.2.1.2 A DSU Biologist (or otherwise titled DNA personnel) will perform appropriate testing in consultation with a DSU Research Biologist and comprehensively record all testing performed.

3.2.2 Testing conducted using non-validated procedures or performed by non-proficiency tested personnel is not eligible for entry into the FBI Laboratory's local, state or national indices of CODIS (i.e., LDIS, SDIS or NDIS).

3.3 Preparing a Letter of Analysis

3.3.1 All LOAs will contain the required elements listed in the LOM practice, such as the required i3 statement, the date of issue, the title of product/subject line, the name of laboratory, and basic contact information for DSU.

3.3.2 Each LOA will be written on FBI letterhead, include "Letter of Analysis" in the title, and contain a header for the conclusions. In addition, the LOA may contain sections for the Introduction/Synopsis, Background, and the detailed DNA Testing Results.

3.3.3 Because the testing included in an LOA is conducted outside some, many, or all of the requirements of the FBI Laboratory's Quality System, a testing caveat that clearly states that results are for investigative lead, intelligence, or other informational purposes only and not suitable for criminal proceedings must be included. In addition to the statement required by the LOM, the following caveat (or an appropriately updated version) will be included in each LOA.

The work described was performed outside the FBI Laboratory's accredited quality system and therefore does not comply with all of the ISO/IEC General Requirements for the Competence of Testing and Calibration Laboratories (17025:2017), the American National Standards Institute (ANSI) National Accreditation Board (ANAB) Accreditation Requirements for Forensic Science Testing and Calibration Laboratories (AR 3125, effective April 29, 2019), or the Quality Assurance Standards for Forensic DNA Testing Laboratories (effective July 1, 2020).

3.3.4 The wording used to convey the contents of the LOA is left to the discretion of the DSU Research Biologist.

3.4 Reviewing the Letter of Analysis

3.4.1 The LOA will be technically reviewed by at least one scientist with expertise in the method(s) utilized for testing. A technical reviewer will review the results to ensure that the conclusions are supported by data and concurrence with the content of the LOA.

3.4.2 The LD DNA Technical Leader (TL) will also be provided the LOA for review and concurrence .

3.5 Upload and Dissemination

3.5.1 The LOA will be uploaded into the FBI's electronic records management system (i.e., Sentinel) under, at minimum, the appropriate case identifier for DSU records. This will be used for tracking purposes. If the testing was on casework evidence for investigative lead, intelligence, or other information purposes, the LOA will also be serialized to the appropriate case ID for the evidence.

3.5.1.1 The technical reviewer(s) and TL will be approvers of the LOA in Sentinel as the record of their review. If a reviewer does not have access to Sentinel (e.g., reviewer external to the FBI, review completed during telework), the review will be recorded (e.g., via email) and retained with the supporting records.

3.5.1.2 If not an approver, the LOA will be distributed in Sentinel to the DSU Chief and any other individual as directed by the DSU Chief.

3.5.2 After review and approval, the contributor, collaborator, external partner, and/or other interested party(ies) will be provided a digital (e.g., via email, via Sentinel) or physical copy of the LOA.

4 Records

Testing and administrative records will be generated and retained in accordance with this procedure and the LOM Practices for Providing Investigative Lead, Intelligence, or Information (i3) Products.

4.1 The following records may be generated::

1) Electronic data in the form of sequencing results (e.g., .bcl, .fastq, .clc.),
2) Written results in the form of tables and/or instrument reports, and
3) Relevant correspondence with contributors.

If generated for an LOA, the applicable records will be retained electronically, generally, in the DSU's electronic records management system (i.e., Laserfiche) indefinitely.

4.2 The DSU Research Biologist is responsible for ensuring all applicable testing and administrative records are appropriately retained and associated to the LOA identifier (i.e., Sentinel serial number).

5 References

FBI Laboratory Operations Manual (LOM)

Rev. #	Issue Date	History
0	04/15/21	New document issued.

Approval

Redacted - Signatures on File

DNA Technical Leader Date: 04/15/2021

DSU Chief Date: 04/15/2021

QA Approval

Quality Manager Date: 04/15/2021